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REMARKS

This response is supplemental to the one Applicants filed on August 10, 2006. Applicants' representative wishes to thank Examiner Bozen for the courteous telephonic conference on today's date wherein she discussed her willingness to review this supplemental amendment.

Applicants have cancelled Claims 1-8 and 11-34 and added new Claims 35-57. Support for the new claims can be found throughout the specification and within the original claims as filed. Method claims 49-57 have been added as they relate to a method of using the isolated compound of Claim 40. Should the Examiner restrict out the newly added method claims, Applicants request rejoinder of those method claims upon allowance of the corresponding compound claims.

Compliance with 35 USC 112

Enablement

The Examiner has indicated, that while the specification enables anti-sense survivin oligonucleotides and anti-survivin antibodies as compounds that inhibit survivin in the presence of HBXIP, undue experimentation would be required to make and use other compounds which are embraced by the claims. Applicants respectfully disagree.

In Regents of University of California v. Eli Lilly & Co., the Federal Circuit held that enablement of a genus under § 112, ¶ 1 may be accomplished by showing the enablement of a representative number of species within that genus. 119 F.3d 1559 (Fed. Cir. 1997). Enablement "is not precluded even if some experimentation is necessary, although the amount of experimentation needed must not be unduly extensive." See Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367 (Fed. Cir. 1986). "To be enabling, the specification of a patent must teach those skilled in the art to make and use the full scope of the claimed invention without 'undue experimentation' ... Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples." See In re Wright, 999 F.2d 1557 (Fed. Cir. 1993).

The specification provides detailed descriptions and working examples of inhibiting survivin by several distinct mechanisms which rely upon an inhibition of HBXIP. Example 6 on

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page 50 of the specification teaches how to use antibodies against HBXIP to inhibit the anti-apoptotic activity of survivin. Additional details on using antibodies are taught beginning on page 20. Example 12 on page 58 details an experiment that teaches one of ordinary skill in the art how to use siRNA against HBXIP to reduce the anti-apoptotic activity of survivin. Additional details on making and using siRNA can be found beginning on page 17 of the specification. How to use antisense nucleic acids is fully taught beginning on page 9. On page 23, the specification fully describes how to make and use small molecules that would inhibit HBXIP in order to inhibit the anti-apoptotic activity of Survivin. Paragraph [66] specifically describes how to screen chemical libraries for those compounds that inhibit survivin. A specific example of how to use a binding assay can be found in Example 4 on page 48.

Accordingly, Applicants have fully taught one of ordinary skill in the art how to make and use many representative species that make up the genus of compounds that reduce the anti-apoptotic activity of survivin by inhibiting the activity of HBXIP. In addition, the detailed examples and description found within Applicants' specification would fully teach one of ordinary skill in the art to make and use small molecule compounds without undue experimentation. While it may take *some* experimentation to discover small molecule compounds that inhibit HBXIP, and therefore reduce the anti-apoptotic activity of Survivin, such experimentation would not be *undue*. Applicants have described a functional screening assay at paragraph [66] and Example 4 that allows one of ordinary skill to quickly determine compounds that would, or would not, function to inhibit survivin. Thus, by showing the enablement of a representative number of species within the genus, and demonstrating that discovering additional species would not require undue experimentation, Applicants have fully enabled their claims. Accordingly, Applicants respectfully request withdrawal of this rejection.

Written Description

The Examiner indicated that while the specification does disclose antisense oligonucleotides and anti-survivin antibodies as compounds that possess the claimed inhibitory activity, it does not describe small molecules and peptide Survivin inhibitors. For that reason, the Examiner argues that Applicants were not in possession of the full scope of the claimed invention.

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In *Falkner v. Inglis*, No. 05-1324 (US Court of Appeals for the Federal Circuit, May 26, 2006) the Federal Circuit concluded that:

> (1) examples are not necessary to support the adequacy of a written description (2) the written description standard may be met (as it is here) even where actual reduction to practice of an invention is absent; and (3) there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of the known structure.

The decision by the Federal Circuit in *Falkner* is in accordance with prior case law, including *Lizard Tech, Inc. v. Earth Resource Mapping, PTY, Inc.* 424 F.3d 1336, 1345 (Fed. Cir. 2005) and *Union Oil Co. v. Atlantic Richfield Co.* 208 F.3d 989, 997 (Fed. Cir. 2000), which concluded, "A claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language."

As discussed in detail above, Applicants' specification demonstrates that they were in possession of a number of species of isolated compounds that inhibit survivin, including antisense compounds, siRNA compounds and antibodies. The Examiner argues that "there is no teaching of small molecules or competitive peptide ligands that inhibit the survivin/HBXIP interaction" (*Office.Action.*, page 5). Although Applicants did not provide a specific working example of using small molecules to inhibit survivin, such an example is clearly not required according to the Federal Circuit (*see Falkner v. Inglis*). All that Applicants need show is that one of ordinary skill in the art would *reasonably* believe that Applicants were in possession of the invention. As discussed previously, specific descriptions of using small molecules is shown under the heading "SMALL MOLECULES" on page 23 of the specification. This, in combination with Applicants description of assays for screening compounds that inhibit HBXIP would lead one of ordinary skill to reasonably believe that Applicants were in possession of their claimed invention.

Applicants' specification describes a multitude of species that would demonstrate to one of ordinary skill in the art that Applicants were in full possession of isolated compounds that inhibit hepatitis B X-interacting protein (HBXIP) which results in a reduced anti-apoptotic activity of survivin. Accordingly, Applicants respectfully request withdrawal of the rejection for lack of written description..

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CONCLUSION

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: August 22, 2006

By: _____

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